

**Notice of Allowability**

Application No.

10/074,178

Applicant(s)

EYRE ET AL.

Examiner

Carolyn L. Smith

Art Unit

1631

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/25/07.
2. ☒ The allowed claim(s) is/are 18-24.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

CAROLYN L. SMITH  
PRIMARY EXAMINER

11/27/07

## **DETAILED ACTION**

### **APPLICANTS' ARGUMENTS**

Amended claims 18 and 21, filed 9/25/07, are acknowledged. Applicants' arguments and amendments, filed 9/25/07, have been fully considered and are persuasive. The species election is hereby withdrawn. All of the previous rejections have been withdrawn.

Claims 18-24 are allowed.

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The invention is directed to a device for determining the presence of a nucleic acid in a sample comprising an instrument for temperature cycling, a fluorimeter for detecting fluorescence, and a processor that is programmed i) to initiate analysis algorithms by inputting into the algorithms fluorescence values measured by the fluorimeter prior to completion of temperature cycling, ii) to initiate a first algorithm to obtain a first score from a first test by inputting into the first algorithm the fluorescence values, iii) to initiate a second algorithm to obtain a second score from a second test by inputting into the second algorithm the fluorescence values, iv) to generate a composite score by evaluating a function that depends on the first score and the second score as independent variables of the function to determine whether the sample is positive or negative for the presence of the nucleic acid, and v) to evaluate the function that depends on the first score

and the second score as independent variables of the function to determine whether the sample is indeterminate for the presence of the nucleic acid. It is noted that page 13, last paragraph, to page 14, first paragraph, of the specification defines the phrase "composite score". The prior art does not disclose the device as it is claimed in the instant invention. The rejections of the previous office action, mailed 3/21/07, are withdrawn due to claim amendments and persuasive arguments. Because no outstanding rejections remain, the claimed invention is deemed allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

#### **EXAMINER INFORMATION**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

November 27, 2007

/Carolyn Smith/  
Primary Examiner  
AU 1631